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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,047	07/23/2001	Glen H. Erikson	E1047/20060	3230
3000	7590	05/10/2005	EXAMINER	
CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/911,047	ERIKSON ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9 and 12-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 March 2005 has been entered.

Status of the Claims

2. This action is in response to papers filed 24 March 2005 in which claims 1, 17-19 and 27 were amended and claims 30-33 were added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 25 October 2004 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-4, 6-9 and 12-33 are under prosecution.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 5-9 and 12-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 (from which Claims 2-4, 6-9, 12-26 and 30-33 depend) has been amended to define probe-target binding as "a homologous duplex, a homologous triplex, a homologous quadruplex, a Watson-Crick triplex or a Watson-Crick quadruplex". Applicant points to page 10, lines 15-19 and page 4, lines 5-6 wherein a co-pending published application is incorporated by reference. The incorporated reference defines triplexes and quadruplexes comprising two complementary target strands (Watson-Crick) complexed with at least one additional strand at least partially homologous to one target strands (§ 65-68). Therefore, the triplex and quadruplex are both homologous and Watson-Crick. The instant claims differentiate between homologous and Watson-Crick triplex and quadruplex by claiming them in the alternative. Therefore, the differentiation introduces new matter.

Claims 17-19 add the recitation "substantially free of Hoogsteen bonding". Applicant has not cited a supporting passage within the specification and a review of the specification, in its entirety, reveals no such support.

Claim 19, further adds "free of G-G quartets". Applicant has not cited a supporting passage within the specification and a review of the specification, in its entirety, reveals no such support.

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Claims 27-29 and 33 add the recitation applying a first/second stimulus "directly".

Applicant has not cited a supporting passage within the specification and a review of the specification, in its entirety, reveals no such support.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

35 U.S.C. 112: second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4, 6-9 and 12-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6-9, 12-26 and 30-33 are indefinite in Claim 1 because it is unclear whether a homologous triplex differs from a Watson-Crick triplex and whether a homologous quadruplex differs from a Watson-Crick quadruplex. Applicant points to the co-pending published and incorporated-by-reference application 2002/0031775 for a supportive teaching of the newly claimed triplexes and quadruplexes. The incorporated reference teaches the triplexes and quadruplexes comprising two complementary target strands (Watson-Crick) complexed with at least one additional strand at least partially homologous to one target

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strands (¶ 65-68). As such, the triplex and quadruplex could be defined both as Watson-Crick and as homologous.

It is further noted that the term homoduplex is routinely used in the art to describe two complementary nucleic acids hybridized to form a duplex. Applicant's claim drawn to a homologous duplex, suggests the claim encompasses complementary nucleic acids. It is suggested that the claims be amended to clearly define the invention.

Claims 17-19 are indefinite for the recitation "substantially free of Hoogsteen bonding" because it is unclear how the recitation further defines the probe-target bonding of Claim 1.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4, 6, 8, 12-13, 15, 17-18, 20-22, 24-25, 27-33 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Cummins et al (U.S. Patent No. 5,874,213, issued 23 February 1999).

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Regarding Claim 1, Cummins et al disclose a method comprising adding probe and target sequences, applying a first stimulus (electrophoresis), detecting a first signal (fluorescence), applying a second stimulus (e.g. UV/VIS) and detecting a second signal and comparing first and second signal to accomplish assay (i.e. identify target based on migration time, Column 13, lines 35-50 and Example 1, Column 13, line 5-Column 14, line 13).

Cummins et al further teach the test sample comprise a label (Column 9, lines 18-57) wherein both stimuli are photonic with an intermediate electronic stimulus (electrophoresis) or the first is electrophoresis and the second is photonic. Cummins teaches capillary electrophoresis (i.e. applied voltage) and illumination for detecting migrating fragments. Hence, the method involves multiple stimuli of both voltage and light meeting the limitations of the claim. Cummins also teach the target and probe form homologous duplex or triplex (Column 8, lines 35-59) and exemplify homothymidine (Example 1, Column 14, line 5-6).

Regarding Claim 2-4, Cummins et al disclose the method comprises capillary electrophoresis (i.e. applied voltage) and illumination over time to detect migrating fragments. Hence, the method involves multiple stimuli of both voltage and light either of which could be defined as a first or second stimuli.

Regarding Claim 6, Cummins et al disclose the method wherein the second stimuli is coextensive with the first i.e. the voltage is on during UV stimulus (Example 1, Column 13, line 5-Column 14, line 13).

Regarding Claim 8, Cummins et al disclose the method wherein the first and second signals are photonic or electronic (Column 10, line 64-Column 11, line 20).

Regarding Claim 12, Cummins et al disclose the method wherein the stimulus is laser (Column 14, lines 40-44).

Regarding Claim 13, Cummins et al disclose the method wherein the electronic stimulus is voltage (Column 14, lines 1-3).

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Regarding Claim 15, Cummins et al disclose the method wherein the label is chemiluminescent (Column 9, lines 36-57 and Column 10, lines 64-67).

Regarding Claim 17, Cummins et al disclose the method wherein the target and probe form a homologous duplex (Column 8, lines 35-59). The claimed "substantially free of Hoogsteen bonding" is given its broadest reasonable interpretation in view of the broad claim language and specification wherein the phrase is not defined. Cummins et al teach binding between complementary sequences and therefore are deemed to be "substantially free" of Hoogsteen bonding.

Regarding Claim 18, Cummins et al disclose the method wherein the target and probe form a DNA/oligomer triplex (Column 8, line 47). While they do not teach the triplex comprises Hoogsteen bonds, the broadly claimed "substantially free" encompasses the presence of such bonds.

Regarding Claim 20, Cummins et al disclose the method wherein the probe comprises an uncharged backbone (Column 8, lines 60-67).

Regarding Claim 21, Cummins et al disclose the method wherein the probe contains an amino acid sequence (Column 4, lines 1-20).

Regarding Claim 22, Cummins et al disclose the method further comprising applying at least one more stimulus and detection (i.e. continual electrophoresis and migration detection encompasses the additional stimulus and detection) (Example 1).

Regarding Claims 24-25, Cummins et al disclose the method wherein the electronic stimulus is not continuous i.e. DCZE (Column 10, line 11).

Regarding Claim 27, Cummins et al disclose a method comprising adding probe and target, applying a first stimulus directly to the sample (electrophoresis), detecting a first signal (fluorescence), applying a second stimulus directly to the sample (e.g. UV/VIS) and detecting a second signal and comparing first and second signal to accomplish assay (i.e. identify target based on migration time, Column 13, lines 35-50 and Example 1, Column 13, line 5-Column

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14, line 13). Cummins et al further teach the test sample comprise a label that is an intercalating agent not covalently bound to the probe or target (Column 9, lines 28-30) wherein both stimuli are photonic with an intermediate electronic stimulus (electrophoresis) or the first is electrophoresis and the second is photonic. Cummins teaches capillary electrophoresis (i.e. applied voltage) and illumination for detecting migrating fragments. Hence, the method involves multiple stimuli of both voltage and light meeting the limitations of the claim.

Regarding Claim 28, Cummins et al disclose the method wherein the probe is a protein or peptide (Column 5, lines 12-19).

Regarding Claim 29, Cummins et al disclose the method wherein the probe is not a biopolymer i.e. they define the oligomer probes as non-naturally occurring (Column 8, lines 35-37 and 60-67).

Regarding Claim 30, Cummins et al disclose the method wherein the label is not covalently bound to the probe or target (Column 9, lines 28-30).

Regarding Claim 31, Cummins et al disclose the method wherein the label is an intercalating agent (Column 9, lines 28-35).

Regarding Claim 32, Cummins et al disclose the method wherein the intercalating agent is not covalently bound to the probe or target (Column 9, lines 28-30).

Regarding Claim 33, Cummins et al disclose the method wherein the first and second stimuli are directly applied to the sample i.e. electrophoresis and UV/VIS (Column 10, lines 1-32).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 7, 9 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummins et al (U.S. Patent No. 5,874,213, issued 23 February 1999) in view of Meade et al (U.S. Patent No. 6,071,699, issued 6 June 2000).

Regarding Claims 7, 9 and 23, Cummins et al disclose a method comprising adding probe and target sequences, applying a first stimulus (electrophoresis), detecting a first signal (fluorescence), applying a second stimulus (e.g. UV/VIS) and detecting a second signal and comparing first and second signal to accomplish assay (i.e. identify target based on migration time, Column 13, lines 35-50 and Example 1, Column 13, line 5-Column 14, line 13) wherein the test sample comprise a label (Column 9, lines 18-57).

Cummins et al further teach the method comprises stimuli via applied voltage for capillary electrophoresis and illumination for detection (UV/VIS) (Column 10, lines 1-33 and line 64-Column 11, line 20). They teach numerous different electronic and photo stimuli and detection means but they do not specifically teach a combined electronic and photo detection (Claims 7 and 9) or more than two different stimuli within one embodiment (Claim 23). However, they do teach that the resolved duplexes are recovered for further analysis (Column 6, lines 23-25 and Example 1) which clearly suggests a third stimulus and different signal detection because the recovered duplexes are no longer within the capillary wherein they were previously detected. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use additional means for stimulating and detecting the recovered duplexes of Cummins et al based on their suggestion to recover them and further based on available detection means.

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11. Claims 14, 16, 19 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummins et al (U.S. Patent No. 5,874,213, issued 23 February 1999) in view of Meade et al (U.S. Patent No. 6,071,699, issued 6 June 2000).

Regarding Claims 14, 16, 19 and 26, the method of Cummins et al discussed above.

Meade et al teach photonic stimuli and electronic via differing combinations of light and/or electronics (Column 35-67). Meade et al teaches an embodiment energy is transferred to generate a signal (Column 24, lines 41-67); wherein at least one label is an electron spin label (Column 23, line 50); wherein the probe and target bind to form a quadruplex (e.g. target, probes and label Fig. 2). Meade et al further provides motivation to use their labeling system wherein they teach greatly enhanced signal-to-noise results wherein pulsed initiation (i.e. repeated stimuli) provides two to four orders of magnitude improvement in signal-to-noise (Column 27, lines 39-50).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the labels and detection of Meade et al to the signal detection of Cummins et al for the expected benefits of obtaining two to four orders of magnitude improvement in signal-to-noise as taught by Meade et al (Column 27, lines 39-50).

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications


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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
May 6, 2005